

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
3 May 2001 (03.05.2001)

PCT

(10) International Publication Number
WO 01/30419 A2

(51) International Patent Classification⁷: A61M 5/00

(21) International Application Number: PCT/GB00/04152

(22) International Filing Date: 30 October 2000 (30.10.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
9925483.1 28 October 1999 (28.10.1999) GB
0018056.2 24 July 2000 (24.07.2000) GB
0026310.3 27 October 2000 (27.10.2000) GB

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(81) Designated States (*national*): AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

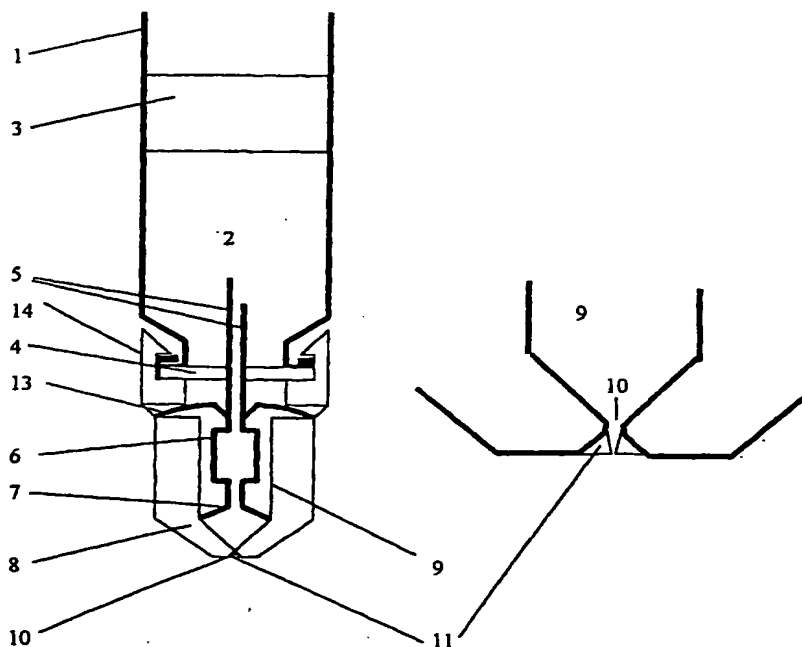
Published:

— Without international search report and to be republished upon receipt of that report.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: DISPOSABLE JET INJECTOR



(57) Abstract: A jet injector is described which clips to the front of a standard drug ampoule and is energised by pressing the assembly against the skin of the patient. The pressure deforms a biaxially curved spring which buckles reversibly to impact the drug delivery tube, causing a high pressure transient. This generates a high speed droplet which cuts a track in the skin. The drug may then be administered with a syringe in the normal manner. An elastomeric non return valve may be incorporated.

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DISPOSABLE JET INJECTOR

Jet injectors have been in use for a long time. In the main, they require a significant amount of drive energy and deliver the dose so rapidly that it causes subcutaneous damage.

- 5 According to the present invention there is jet injector which is energised by pressing the device against the skin of the patient. The pressure deforms a biaxially curved spring which may relax by reversibly buckling. The fast moving relaxing spring may impact on a crimp in a drug delivery tube to generate a high pressure at the nozzle end. The nozzle end of the drug delivery tube may be flared to form a small piston
- 10 within a cylinder comprising the exit nozzle. The exit nozzle may be in the form of a slit or non circular cross section. There may be an elastomeric non return valve to prevent ingress of infection or air. The device may clip onto the ampoule in such a manner that removal will cause such damage that the system becomes inoperable. A point contact of the nozzle on the skin may provide not only a good hydraulic seal but
- 15 also generate a radially decreasing stress distribution within the soft tissue which will ensure that the drug is delivered to the full depth of the track. The biaxially curved spring may be so formed as to provide a high mechanical advantage leverage system to reduce the forces applied to the skin of the patient.
- 20 Jet injectors have been in use for over half a century. A high velocity droplet of fluid may pierce the skin and cut a track through the soft subcutaneous tissue. A problem of the earlier injectors was that a jet of fluid fast enough to cut the toughest of skins would also penetrate too deeply, especially for drugs like insulin that must be deposited in the subcutaneous fat layer. By using a single droplet, viscous forces
- 25 attenuate it rapidly, so providing aggressive cutting at the dermis but ensuring controllable range. This effect may be enhanced by use of a planar jet from a slit like nozzle.

- Most jet injectors use a significant power source. Compressed gas is a favourite,
- 30 though springs and even explosive charges have been used. In the present device, a spring is used, though the cutting drop is of such a small volume that just pressing the device against the skin is sufficient to cock and fire the device.

There is a biaxially curved spring. This is compressed by applying a couple at the edge. The stress in the spring increases until it is almost planar at which point it buckles reversibly and turns inside out. The centre of the spring is travelling very fast at the minimum energy configuration. If there is a hole through the centre of the spring
5 such that it may travel along the drug delivery tube, it may be arranged that the centre of the spring may impact on a crimp in the drug delivery tube creating a very high transient load. This load will be transmitted to the end of the drug delivery tube where it may actuate a micro piston to eject a fast droplet of drug.

- 10 The main dose may be delivered manually from the ampoule in the usual manner, by depressing the piston. This may be done very slowly to minimise soft tissue damage. A silicone non return valve may be fitted at the nozzle. This will inhibit back flow of material that might cause cross infection. It will also inhibit inflow of air due to thermal contraction of the fluid in the ampoule. Air in the delivery tube would inhibit
15 the pump operation.

An embodiment is shown in section in figure 1, with an enlarged view of the nozzle and valve for clarity. There is an ampoule, 1, with liquid drug, 2, rubber piston, 3, and rubber septum, 4, disposed in the usual configuration. There is a drug delivery
20 tube, 5, which pierces the septum, 4. This has a crimp, 6, midway along its length and a flare, 7 at the outlet end. There is an injection moulded end cap, 8, which comprises, a cylinder, 9, and nozzle, 10. There is also an elastomeric non return valve, 11, on the outer surface, 12. There is a biaxially curved stainless steel spring, 13, and an injection moulded holder, 14. The holder clips onto the ampoule as the drug delivery
25 tube pierces the ampoule. The holder, 14, and end cap, 8, may clip together or be the same moulding with a bayonet fitting to accept a somewhat rectangular shaped spring together with a flexible connection to permit compression of the spring.

In operation, the ampoule piston is advanced with the system held vertically to expel
30 any air. The end cap is then pressed against the skin of the patient which in turn flattens the biaxially curved spring. This then pops through the maximum strain configuration and accelerates toward impact with the drug delivery tube. The impact is conducted along the tube to the flared end and the drug in the cylinder, 9, is subject to a very high pressure. This high pressure ejects a droplet of drug through the

nozzle, the elastomeric non return valve and the skin of the patient. A pressure wave will also propagate up the delivery tube into the ampoule. The constriction associated with the crimp will attenuate this. The change in internal diameters of the crimp and ampoule will ensure that the pressures transmitted to the ampoule will be very small

5 indeed.

There will be a click indicating that the spring has fired and produced a track. The piston in the ampoule may then be depressed to deliver the drug. In the unlikely event of an unsuccessful pierce, it will be impossible to depress the plunger, the hydraulic seal of the nozzle to the skin being good to several atmospheres. Should the pressure be inadvertently removed, the spring will click back to its original position indicating that the injection is over. The balance of the injection may be repeated at a new site.

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The biaxially curved spring may be any desired shape. It may also be cut or formed in such a fashion that the end cap may exert a small force over a large distance to complete compression, so reducing the loading on the skin of the patient. The zone around the hole may be formed in a conical shape to more effectively spread the load on impact. If the spring has a rectangular planform, it may be fitted to an integral holder, 14, and end cap, 8, assembly by insertion and rotation by 90°. In addition, the raising of the angled tips about the pressure point of the holder will provide a significant amount of travel, so reducing the load at the injector skin interface required to cock the device.

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The holder 14 may have a number of radially disposed clips, as shown, engineered so that clipping to the ampoule takes the root of the cantilever clip close to its failure strain. It will be difficult to splay a number of such clips simultaneously to remove the injector. Any effort to splay them is likely to exceed the strength of the carefully engineered cantilevers, causing them to snap off. In this manner, the injector cannot be re-used. This will reduce the risk of infection and will also prevent use with a rival manufacturers ampoules.

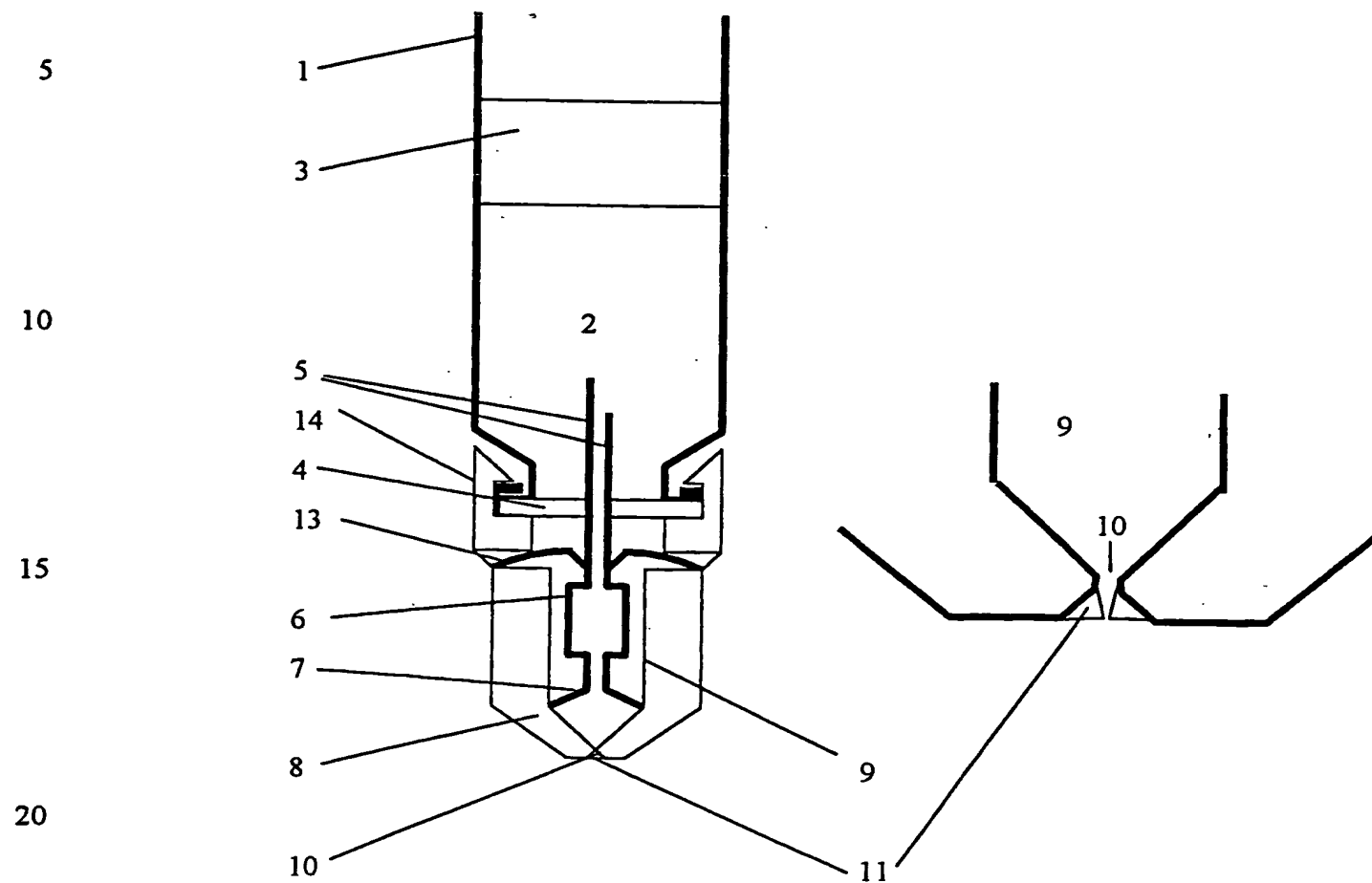
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CLAIMS

1. A jet injector which is energised by pressing the device against the skin of the
5 patient.
2. A jet injector powered by a biaxially curved spring which compressed by flattening
with a couple at the periphery and in which the compression energy is converted into
kinetic energy by reversibly buckling past the flattened configuration.
10
3. A jet injector according to the claims 1 and 2 in which the fast moving biaxially
curved spring may impact on a crimp in a drug delivery tube to generate a transient
high pressure.
- 15 4. A jet injector according to claims 1 to 3, in which the nozzle end of the drug
delivery tube may be flared to form a small piston within a cylinder which comprises
the exit nozzle.
5. A jet injector in which the exit nozzle may be in the form of a slit or non circular
20 cross section.
6. A jet injector according to the claims 1 to 5 which incorporates an elastomeric non
return valve to prevent ingress of infection or air.
- 25 7. A jet injector according to claims 1 to 6, which may clip onto an ampoule in such a
manner that removal will cause such damage that the system becomes inoperable.
8. A jet injector that exerts a point contact of the nozzle on the skin to provide both a
good hydraulic seal and also a radially decreasing stress distribution within the
30 underlying soft tissue which will ensure that the drug is delivered to the full depth of
the track.

9. A jet injector that comprises a biaxially curved spring formed to provide a high mechanical advantage leverage system which permits cocking with a small force operating through a large distance.

Figure 1

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
3 May 2001 (03.05.2001)

PCT

(10) International Publication Number
WO 01/30419 A3

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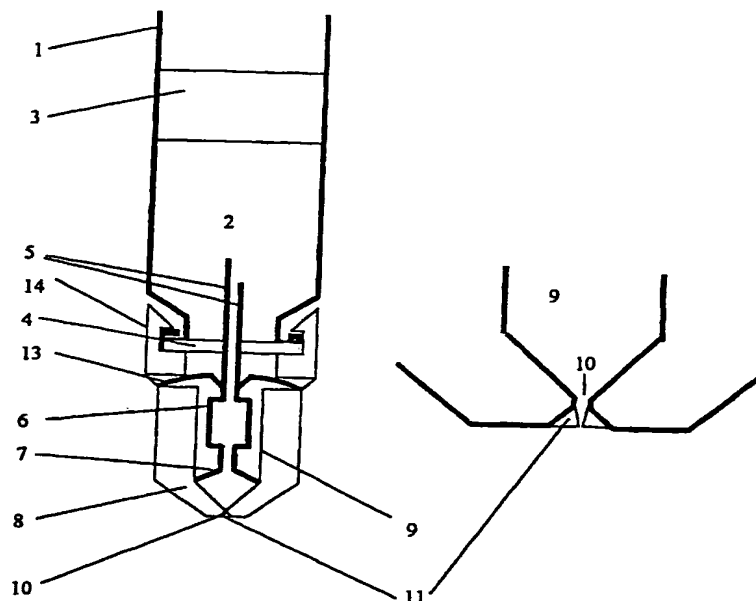
Published:

— with international search report

(88) Date of publication of the international search report:
20 September 2001

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(57) Abstract: A jet injector is described which clips to the front of a standard drug ampoule (1) and is energised by pressing the assembly against the skin of the patient. The pressure deforms a biaxially curved spring (13) which buckles reversibly to impact the drug delivery tube (5), causing a high pressure transient. This generates a high speed droplet which cuts a track in the skin. The drug may then be administered with a syringe in the normal manner. An elastomeric non return valve (11) may be incorporated.

WO 01/30419 A3

INTERNATIONAL SEARCH REPORT

Intern Application No

PCT/GB 00 52

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M5/30 A61M5/31 A61M5/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 18425 A (BAILEY WILLIAM JOHN ; REID DOMINIC AUGUSTINE (GB); DENNE WILLIAM AN) 20 June 1996 (1996-06-20) page 10, line 4 - page 13, line 25; figures 6-9	1,5-8
Y		2-4,9
Y	US 4 677 600 A (YOSHIDA MOTOHIKO) 30 June 1987 (1987-06-30) column 2, line 39 - line 52; figures 4-8	2-4,9

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- * & * document member of the same patent family

Date of the actual completion of the international search

6 April 2001

Date of mailing of the international search report

18/04/2001

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/04152

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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US 4677600	A	30-06-1987	JP 61138420 A	25-06-1986
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